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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,654	12/21/2001	Birgit Jung	1/1178	7012

28501 7590 07/14/2003

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

029,654

Applicant(s)

BIRCH et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 4/21/03
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-29 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☐ Claim(s) is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☒ Claim(s) 1-29 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644.

Claims 1-29 are pending.

Applicant's election without traverse of Group I (claims 1-13) in Paper No. 7 is acknowledged. However, upon reconsideration, the present examiner has restricted as follows:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to determining if a substance is an activator or inhibitor of MIF, classified in class 435, subclass 7.21 and 29.
- II. Claims 1-8, drawn to determining if a substance is an activator or inhibitor of DAD1, classified in class 435, subclass 15 and 29.
- III. Claims 1-8, drawn to determining if a substance is an activator or inhibitor of ARL4, classified in class 435, subclass 5 and 29.
- IV. Claims 1-8, drawn to determining if a substance is an activator or inhibitor of GNS, classified in class 435, subclass 18 and 29.
- V. Claims 1-8, drawn to determining if a substance is an activator or inhibitor of Transglutaminase 2, classified in class 435, subclass 16 and 29.
- VI. Claims 1-8, drawn to determining if a substance is an activator or inhibitor of UDP-Glucose Ceramide Glycosyltransferase, classified in class 435, subclass 15 and 29.
- VII. Claims 1-8, drawn to determining if a substance is an activator or inhibitor of Stearyl-CoA-Desaturase, classified in class 435, subclass 26.

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- VIII. Claims 9-13, drawn to determining the expression level of MIF in macrophages, classified in class 435, subclass 7.21.
- IX. Claims 9-13, drawn to determining the expression level of DAD1 in macrophages, classified in class 435, subclass 15.
- X. Claims 9-13, drawn to determining the expression level of ARL4 in macrophages, classified in class 435, subclass 5.
- XI. Claims 9-13, drawn to determining the expression level of GNS in macrophages, classified in class 435, subclass 18.
- XII. Claims 9-13, drawn to determining the expression level of Transglutaminase 2 in macrophages, classified in class 435, subclass 16.
- XIII. Claims 9-13, drawn to determining the expression level of UDP-Glucose Ceramide Glycosyltransferase in macrophages, classified in class 435, subclass 15.
- XIV. Claims 9-13, drawn to determining the expression level of Stearyl-CoA-Desaturase in macrophages, classified in class 435, subclass 26.
- XV. Claims 14-20, drawn to a substance determined to be an activator or inhibitor of MIF, classified in class 514, subclass 1+.
- XVI. Claims 14-20, drawn to a substance determined to be an activator or inhibitor of DAD1, classified in class 514, subclass 1+.
- XVII. Claims 14-20, drawn to a substance determined to be an activator or inhibitor of ARL4, classified in class 514, subclass 1+.

- XVIII. Claims 14-20, drawn to a substance determined to be an activator or inhibitor of GNS, classified in class 514, subclass 1+.
- XIX. Claims 14-20, drawn to a substance determined to be an activator or inhibitor of Transglutaminase 2, classified in class 514, subclass 1+.
- XX. Claims 14-20, drawn to a substance determined to be an activator or inhibitor of UDP-Glucose Ceramide Glycosyltransferase, classified in class 514, subclass 1+.
- XXI. Claims 14-20, drawn to a substance determined to be an activator or inhibitor of Stearyl-CoA-Desaturase, classified in class 514, subclass 1+.
- XXII. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an activator of MIF, classified in class 514, subclass 1+.
- XXIII. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an activator of DAD1, classified in class 514, subclass 1+.
- XXIV. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an activator of ARL4, classified in class 514, subclass 1+.
- XXV. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an activator of GNS, classified in class 514, subclass 1+.
- XXVI. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an activator of Transglutaminase 2, classified in class 514, subclass 1+.
- XXVII. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an activator of UDP-Glucose Ceramide Glycosyltransferase, classified in class 514, subclass 1+.

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- XXVIII. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an activator of Stearyl-CoA-Desaturase, classified in class 514, subclass 1+.
- IXXX. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an inhibitor of MIF, classified in class 514, subclass 1+.
- XXX. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an inhibitor of DAD1, classified in class 514, subclass 1+.
- XXXI. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an inhibitor of ARL4, classified in class 514, subclass 1+.
- XXXII. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an inhibitor of GNS, classified in class 514, subclass 1+.
- XXXIII. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an inhibitor of Transglutaminase 2, classified in class 514, subclass 1+.
- XXXIV.. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an inhibitor of UDP-Glucose Ceramide Glycosyltransferase, classified in class 514, subclass 1+.
- XXXV. Claims 21-29, drawn to a method of treating an inflammatory disease by administration of an inhibitor of Stearyl-CoA-Desaturase, classified in class 514, subclass 1+.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I and each of II-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to screening for activators/ inhibitors of distinct proteins/enzymes. Methods of screening for activators /inhibitors of each of these proteins/enzymes would involve the use of different reagents and different steps. Motivation to screen for activator/inhibitors of each of these proteins/enzymes would be different, and a reference showing an assay for activators/inhibitors of one such protein/enzyme would not suggest assays for activators /inhibitors of the other proteins/enzymes.

Inventions VIII and each of IX-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions detect the levels of distinct proteins/enzymes. Each invention uses different reagents and steps. A reference teaching detection of the level of one of these proteins/enzymes need not suggest the detection of the level of any of the other proteins/enzymes.

Inventions I-VII and VIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because they use different reagents and steps and achieve different ends. A reference showing a detection of the level of a protein need not suggest or motivate one to assay for activator/inhibitors of that protein, since it is common in the art for a

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reference to merely teach the determination of a protein level as a diagnostic marker of a disease state.

Inventions I-VII and XV-XXI are related as process of making (screening for) and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the activator /inhibitor products could have already existed, without recognition of their function in relation to the recited proteins/enzymes.

Inventions XV-XXI and XXII-XXXV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case activators or inhibitors of Groups XV-XXI would have other uses. For example, inhibitors of enzymes can be used in vitro—e.g. to inhibit an enzyme reaction when one wishes to detect the activity of a similar enzyme in a histological section.

Inventions XXII-XXVIII and XXIX-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ by virtue of respectively activating or inhibiting the functioning of a particular protein/enzyme in vivo. A reference teaching the administration of an



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activator for one of the recited proteins/enzymes would teach away from the administration of an inhibitor for the same protein/enzyme and visa versa.

Inventions XXII and each of XXIII-XXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions serve to activate the functions of distinct proteins/enzymes in vivo. A reference teaching the administration of an activator for one of these proteins/enzymes need not suggest the administration of an activator for another of these proteins/enzymes.

Inventions XXIII and each of XXIX-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions serve to inhibit the functions of distinct proteins/enzymes in vivo. A reference teaching the administration of an inhibitor for one of these proteins/enzymes need not suggest the administration of an inhibitor for another of these proteins/enzymes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different required searches, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: distinct activators/inhibitors for each one of the proteins/enzymes recited in Groups XV-XXXV. Each of these groups encompasses a multitude of possible undefined and

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undescribed activators/inhibitors per se or to in vivo uses thereof. Applicant is required to elect a particular activator or a particular inhibitor for the Group elected among Groups XV-XXXV.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims XV-XXXV are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976. The examiner can normally be reached on Mon.-Thu., 8:00 am-5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone number for the organization where this application is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAS  
July 11, 2003

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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